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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,469	10/20/2003	Patrice Debregeas	065691-0339	4165

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EXAMINER	
HUYNH, CARLIC K	

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1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,469	DEBREGEAS ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on July 5, 2007 is acknowledged.

Status of the Claims

1. Claims 1-12 are pending in the application in response to the Non-Final Rejection submitted on March 8, 2007. Applicants' Amendment- After Non-Final Rejection filed on July 5, 2007, has been acknowledged. Applicants have amended claim 9 in an Amendment- After Non-Final Rejection filed on July 5, 2007. Accordingly, claims 1-12 are being examined on the merits herein.

Response to Arguments

2. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on July 5, 2007, with respect to "Amendments to the Specification" to the objection to the usage of trademarks in the specification have been fully considered and are persuasive. The specification has been amended to capitalize trademarks and include the chemical names of the trademarks. The following trademarks were amended: EUDRAGIT and AQUACOAT in paragraph [0026]; EUDRAGIT NE 30D, EUDRAGIT E 100, and PHARMACOAT in paragraph [0027]; and PVP K30 in paragraphs [0052], [0054]-[0055], and [0061]. Thus, the Objection to the Specification, in its entirety, has been withdrawn in light of the amendments.

3. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on July 5, 2007, with respect to "Claim objection" to claim 9 has been fully considered and are persuasive.

Claim 9 has been amended to correct the spelling of "Gingko". Thus, the Claim Objection to claim 9 has been withdrawn in light of the amendments.

4. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on July 5, 2007, with respect to "Rejections under 35 U.S.C. § 103 (Obviousness rejection)" to claims 1-12 has been fully considered and are not found persuasive. The Applicants have argued that the Restriction Requirement and the Non-Final Rejection are contradictory. In the Restriction Requirement, it was stated that:

> "It is noted that the species of a neutral core and the species of plant substances are structurally distinct and the search for each neutral core and the search for each plant substance would represent an undue burden on the Office. The neutral core may be selected from, for example, sugar, starch, mannitol, sorbitol, xylitol, cellulose, or talc. The plant substance may be selected from, for example, garlic, Ginko biloba, ginseng, Harpagpphytum, St. John's wort, green tea, valerian, or Orthosiphon".

The Applicant was required to elect (1) a single species of the neutral core, which was to be selected from, for example, sugar, starch, mannitol, sorbitol, xylitol, cellulose, or talc. The Applicant was also required to elect (2) a single species of the plant substance, which was to be selected from, for example, garlic, Ginko biloba, ginseng, Harpagpphytum, St. John's wort, green tea, valerian, or Orthosiphon. The Applicant had elected mannitol as the specific specie of the neutral core and Ginko biloba as the specific specie of the plant substance. The election of species did neither convey nor intended to convey a combination of neutral core and plant substance.

In the Rejections under 35 U.S.C. § 103 to claims 1-12, Menzi et al. (6,056,949) taught carbohydrates, e.g. sugars or chemically modified starches such as sucrose (column 2, lines 11-12 and 22-23), but did not teach mannitol specifically. Nissenson et al. (The Western Journal of Medicine, 1979, Vol. 13, No. 1, pp. 277-284) taught mannitol is a carbohydrate (p. 277). The application of the references Menzi et al. and Nissenson et al. follow standard practice for Rejections under 35 U.S.C. § 103 to combine these two references.

Thus, the Rejections under 35 U.S.C. § 103 to claims 1-12 stand rejected under Menzi et al. in view of Nissenson et al.

5. Applicant's arguments, see "Amendment-After Non-Final Rejection" filed on July 5, 2007, with respect to "Obviousness Double Patenting (ODP) Rejections" to claims 1 and 12 have been fully considered and are found persuasive in its entirety. Debregeas et al. (Re. 35,903), Debregeas et al. (4,960,596), Debregeas et al. (5,385,739), Leduc et al. (5,549,911), Debregeas et al. (6,077,544), Debregeas et al. (6,139,877), DeBregeas et al. (6,228,395), Debregeas et al. (6,383,516), Debregeas et al. (6,458,389), Debregeas et al. (6,482,437), Debregeas et al. (6,551,621), Debregeas et al. (6,660,296), and Debregeas et al. (6,770,298) are not obvious over the instant invention. Thus the ODP Rejection to claims 1 and 12 are withdrawn.

6. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection. The following new ground(s) of rejection to amended claims 1-12 are used herewith.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menzi et al. (6,056,949), in view of Nissenson et al. (The Western Journal of Medicine, 1979, 131, pp. 277-284), Debregeas et al. (4,960,596), De Long et al. (6,030,621) and DeBregeas et al. (U.S. Patent 6,228,395).

Menzi et al. teach flavorant or odorant granules of natural (vegetable or animal) or synthetic origin with a particle size of 20 to 3000 μm in diameter (column 2, lines 9-10 and lines 60-61). The core can be used with carbohydrates, e.g. sugars, chemically modified sugars or starches such as sucrose, or sugar alcohols (column 2, lines 11-12 and 22-23).

Menzi et al. also teach that the particles can be coated after granulation by spraying a solution of polyvinylpyrrolidone (column 2, lines 40-47). The coated particles may contain other pharmaceutically acceptable excipients such as dyes, vitamins, etc. (column 2, lines 35-36).

Menzi et al. teach that such granules are used as flavorants and odorants (column 2, line 57).

Menzi et al. do not teach the neutral core having a starch/sucrose core in a 20/80 mass ratio, which is coated with 80% by weight of starch.

Menzi et al. also do not teach the controlled or delay release from the granule, or granules containing ethylcellulose with a plasticizer or hydroxypropylmethylcellulose.

Menzi et al. also do not teach the plant substance, the weight of the plant substance to the total weight of the granule, or the granule having multiple layers.

Although Menzi et al. do not teach mannitol specifically, Nissenson et al., teach mannitol is made from the carbohydrate, or sugar, namely dextrose, and is a well-known sugar alcohol (p. 277). Mannitol is a modified sugar and as such, it is reasonably expected that a composition of any sugar, e.g. sucrose from the composition of Menzi et al., would yield the same composition comprising a sugar substance as recited in the instant claim 2.

Although Menzi et al. do not teach granules made from Gingko biloba extracts specifically, De Long et al. teach granules made from Ginkgo biloba extracts and that the weight of such extracts account for 4% of the total weight of the granule (abstract and column 16. lines 55-65).

Debregeas et al. teach granules that are coated with ethylcellulose and capable of a controlled release of Diltiazem (column 4, lines 4-10).

DeBregeas et al. teach bi-layered granules capable of rapid release and granules capable of slow release (column 2, lines 10-24). These granules are coated with hydroxypropylmethylcellulose and contain a plasticizer and a binder (column 2, line 50; column 3, lines 30-31; and column 4, lines 20-24).

DeBregeas et al. also teach a starch/sugar weight ratio in the region of 75/25, with the starch accounting for 75% by weight (column 3, lines 11-12).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the granule composition of Menzi et al. to contain Ginkgo biloba extract, to be coated with ethylcellulose as to allow for controlled release, to be coated with

hydroxypropylmethylcellulose as to allow for slow release, and to contain a sugar because the granules of De Long et al. contain Ginkgo biloba extracts, the granules of Debregeas et al. contain ethylcellulose which allows for controlled release, the granules of DeBregeas et al. contain hydroxypropylmethylcellulose which allows for slow release, and the composition of Nissenson et al. contain mannitol which is a modified sugar and according to De Long et al., Debregeas et al., and DeBregeas et al., the granules contain Ginkgo biloba extracts and according to Nissenson et al., mannitol is a modified sugar.

The motivation to combine the granule composition of Menzi et al. to the granules of De Long et al., Debregeas et al., and DeBregeas et al. as well as the mannitol of Nissenson et al. is that the granules of De Long et al. contain Ginkgo biloba extracts, the granules of Debregeas et al. contain ethylcellulose which allows for controlled release, the granules of DeBregeas et al. contain hydroxypropylmethylcellulose which allows for slow release, and the composition of Nissenson et al. contain mannitol which is a modified sugar.

Regarding the mass ratio of the starch/sucrose core and the weight of the starch as recited in the instant claim 3, it is noted that DeBregeas et al. teach the mass ratio of starch/sucrose in the region of 75/25 and the starch content at 75%, which closely meets the mass ratio of starch/sucrose and the starch content set forth in instant claim 3. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of chromium picolinate provided in a composition, according to the guidance set forth in Boynton et al., to provide a composition having desired chromium content. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the content of the plant substance as recited in instant claim 10, it is noted that between 0.1 mg/g and 750 mg/g weight of plant substance to the total weight of the granule is equivalent to 0.01% to 75% by weight of plant substance in the granule.

Conclusion

8. No claims are allowable.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI JUNWA... ...MINEX...

ckh